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LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			ART UNIT 1646	PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/020,648

Applicant(s)

STROM, TERRY B.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 11-13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

#### ***Election/Restrictions***

1. Applicant's election without traverse of Group IV (claims 8-10, 14) on 3/24/2004 is acknowledged.

Claims 1-7, 11-13, 15, are withdrawn from further consideration by the examiner, as being drawn to a non-elected invention.

#### ***Specification***

2. Applicants are requested to update the status of the prior applications to which the instant application is claiming benefit. The status of nonprovisional parent 08/975,563 should be updated and the expression, "now U.S. Patent No. 6,113,900" should follow the filing date of the parent application.

#### ***Claim rejections-35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 3a. Claims 8-10, 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The written description in this case only sets forth a method of inhibiting the T-lymphocyte-induced rejection of a skin or heart allograft in a mammal comprising administering to said mammal, following said allograft an IL-2 receptor specific antibody or IL-2 linked to a cytotoxin, which have a specific affinity for IL-2 receptors on T lymphocytes wherein the antibody or IL-2 linked to a cytotoxin has the ability to effect the lysis of said T-lymphocytes. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Claim 8 as recited encompasses any substance that has a specific affinity for IL-2 receptors, which includes various compounds having structural similarity to IL-2 and can interfere with IL-2 binding to its receptor. However, Applicants have only provided a written description of a method comprising administering to said mammal, following said allograft, an IL-2 receptor specific antibody or IL-2 linked to a cytotoxin, which have a specific affinity for IL-2 receptors on T lymphocytes wherein the antibody or IL-2 linked to a cytotoxin has the ability to effect the lysis of said T-lymphocytes. Furthermore, in the instant specification, there is no description for IL-2 receptor-specific analog linked to a cytotoxin as recited in claim 14. Page 11 of the specification, only discloses administration of IL-2 itself together with the IL-2

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receptor antibody and page 13 discloses that the lytic factor can be IL-2 linked to a toxin like ricin or diphtheria toxin. However, no disclosure, beyond the mere mention of administering native IL-2 bound to a toxin is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only a method of inhibiting the T-lymphocyte-induced rejection of a skin or heart allograft in a mammal comprising administering to said mammal, following said allograft an IL-2 receptor specific antibody or IL-2 linked to a cytotoxin, which have a specific affinity for IL-2 receptors on T lymphocytes wherein the antibody or IL-2 linked to a cytotoxin has the ability to effect the lysis of said T-lymphocytes, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. As a result, it does not appear that the inventors were in possession of a method as cited in claims 8-10, 14.

3b. Claims 8-10, 14, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the T-lymphocyte-induced rejection of a skin or heart allograft in a mammal comprising administering to said mammal, following said allograft an IL-2 receptor specific antibody or IL-2 linked to a cytotoxin, which have a specific affinity for IL-2 receptors on T lymphocytes wherein the antibody or IL-2 linked to a cytotoxin has the ability to effect the lysis of said T-lymphocytes, does not reasonably provide enablement for a method of administering "all" substances having affinity for IL\_2 receptors as recited in claim 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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The specification delimits the instant method to administering IL-2 receptor specific antibody or IL-2 linked to a cytotoxin. However, with respect to claims 8-10 as recited, what is claimed in the instant invention broadly encompasses a method of administering "all" substances that have specific affinity for IL-2 receptors and can affect the lysis of T-lymphocytes. The specification is non-enabling for a method of administering the unlimited number of substances that can bind to IL-2 receptors, and which are encompassed by the scope of the claims. Claim 8 is a single means claim (M.P.E.P. 2164.08(a)). In In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), the Courts have held that: "A single means claim, i.e. where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph." (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor). Since no material limitations for the "substance" have been recited in the claim and only a biological activity has been recited, the claim encompasses every conceivable structure (means) for achieving the stated property (result), a fact situation comparable to Hyatt. Therefore, not only proteins, such as antibodies against IL-2 receptor, but all other substances, which exhibit an antagonistic activity to IL-2 receptors, are encompassed by the scope of the claim. The claimed invention encompasses a method of administering compositions not envisioned or described in the specification, and neither does the specification disclose how these compositions can be distinguished from each other. The specification only enables a method of administering IL-2 receptor specific antibody or IL-2 linked to a cytotoxin, these polypeptides having specific characteristics and properties. These properties may differ structurally, chemically and physically

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from other known proteins. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine which other proteins are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little, thereby rendering the results of the assays taught in the specification unpredictable (see pages 6-9). Therefore, it would require undue experimentation to determine which substances having specific affinity for IL-2 receptor, would be encompassed by the scope of the method claims. The disclosure of these two polypeptides is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims, which encompass a method of administering every and all IL-2 receptor binding compositions, including analogs of IL-2 bound to cytotoxins. In In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), the Courts have held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides

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broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Furthermore, the amount of embodiments corresponding to the desirable compositions, may be innumerable, and the enabled embodiments amount to only two. Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe administering any other polypeptides other than IL-2 receptor specific antibody or IL-2 linked to a cytotoxin, and since it is deemed to constitute undue experimentation to determine all the others, the disclosure is not commensurate with the scope of the claims. It is suggested that by employing conventional claim language, the method claims be amended to include the specific polypeptides supported by the instant specification.

***Claim rejections-35 USC § 112, second paragraph***

4. Claims 8-10, 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is vague and indefinite for several reasons.

Claim 8, line 3, recites "characterized" which recitation renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).



Claim 8, line 1, recites the limitation “the T-lymphocyte-induced”. There is insufficient antecedent basis for this limitation in the claim.

Claim 10, line 4, recites “characterized” which recitation renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 14, line 2, recites “analog” which is vague and indefinite because the metes and bounds of this term are unclear.

***Claim rejections-Double Patenting***

***Non-statutory double patenting rejection (obviousness-type)***

5. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5a. Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-6 of U.S. Patent No. 5,011,684. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 4 of U.S. Patent No. 5,011,684 (having the common inventor with the instant application), claims a method of inhibiting allograft rejection in a mammal by administering a monoclonal antibody to the IL-2 receptor. In instant claims 8-10, a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor is claimed. Instant claims 8-10 are generic to claims 4-6 in the patent and encompasses subject matter to which the allowed claims are a species because a method as recited in claims 8-10 encompasses the method of claims 4-6 of the patent. However, the patent claim is obvious from the instant claim because the patent claim is directed to one specific embodiment encompassed by instant claims 8-10. The patented product is included in instant claims 8-10. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor included a method of inhibiting allograft rejection in a mammal by administering a monoclonal antibody to the IL-2 receptor. The patented claims if infringed upon would also result in infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

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5b. Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,916,559. Although the conflicting claims are not identical, they are not patentably distinct from each other. Independent claims 1, 6, 10 of U.S. Patent No. 5,916,559 (having the common inventor with the instant application), claim a method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor. In instant claims 8-10, a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor is claimed. Instant claims 8-10 are generic to claims 1-17 in the patent and encompasses subject matter to which the allowed claims are a species because a method as recited in claims 8-10 encompasses the method of claims 1-17 of the patent. However, the patent claim is obvious from the instant claim because the patent claim is directed to one specific embodiment encompassed by instant claims 8-10. The patented product is included in instant claims 8-10. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor included a method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor. The patented claims if infringed upon would also result in infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

5c. Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,113,900. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of U.S. Patent No. 6,113,900 (having the common inventor with the instant application), claims a

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method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor. In instant claims 8-10, a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor is claimed. Instant claims 8-10 are generic to claims 1-9 in the patent and encompasses subject matter to which the allowed claims are a species because a method as recited in claims 8-10 encompasses the method of claims 1-9 of the patent. However, the patent claim is obvious from the instant claim because the patent claim is directed to one specific embodiment encompassed by instant claims 8-10. The patented product is included in instant claims 8-10. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor included a method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor. The patented claims if infringed upon would also result in infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

5d. Claims 8-10, 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-20 of U.S. Patent No. 6,113,900. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 10 of U.S. Patent No. 6,113,900 (having the common inventor with the instant application), claims a method of inhibiting allograft rejection in a mammal by administering a cytotoxin linked to an IL-2 receptor-specific substance. In instant claims 8-10, 14, a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor is claimed. Instant claims 8-10, 14 are generic to claims 10-20 in the patent and

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encompasses subject matter to which the allowed claims are a species because a method as recited in claims 8-10, 14 encompasses the method of claims 10-20 of the patent. However, the patent claim is obvious from the instant claim because the patent claim is directed to one specific embodiment encompassed by instant claims 8-10, 14. The patented product is included in instant claims 8-10, 14. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of inhibiting allograft rejection by administering a cytotoxin linked to a substance that has specific affinity to the IL-2 receptor included a method of inhibiting allograft rejection in a mammal by administering a IL-2 linked to a cytotoxin which cytotoxin linked IL-2 is a specific substance that can bind to the IL-2 receptor. The patented claims if infringed upon would also result in infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

5e. Claims 8-10, 14, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,336,489. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of U.S. Patent No. 5,336,589 (having the common inventor with the instant application), claims a method of inhibiting allograft rejection in a mammal by administering a cytotoxin linked to an IL-2 specific substance. In instant claims 8-10, a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor is claimed. Instant claims 8-10 are generic to claims 1-5 in the patent and encompasses subject matter to which the allowed claims are a species because a method as recited in claims 8-10 encompasses the method of claims 1-5 of the patent. However, the patent claim is obvious from the instant claim because

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the patent claim is directed to one specific embodiment encompassed by instant claims 8-10. The patented product is included in instant claims 8-10. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor included a method of inhibiting allograft rejection in a mammal by administering a cytotoxin linked to an IL-2 specific substance. The patented claims if infringed upon would also result in infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

5f. Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,336,489. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-4, 6 of U.S. Patent No. 5,336,489 (having the common inventor with the instant application), claims a method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor. In instant claims 8-10, a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor is claimed. Instant claims 8-10 are generic to claims 1-4, 6 in the patent and encompasses subject matter to which the allowed claims are a species because a method as recited in claims 8-10 encompasses the method of claims 1-4, 6 of the patent. However, the patent claim is obvious from the instant claim because the patent claim is directed to one specific embodiment encompassed by instant claims 8-10. The patented product is included in instant claims 8-10. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of inhibiting allograft rejection

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by administering a substance that has specific affinity to the IL-2 receptor included a method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor. The patented claims if infringed upon would also result in infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

5g. Claims 8-10, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,587,162. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-10 of U.S. Patent No. 5,587,162 (having the common inventor with the instant application), claims a method of inhibiting T-lymphocyte induced allograft rejection in a mammal by administering an antibody to the IL-2 receptor wherein the antibody is linked to a cytotoxin. In instant claims 8-10, a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor is claimed. Instant claims 8-10 are generic to claims 1-10 in the patent and encompasses subject matter to which the allowed claims are a species because a method as recited in claims 8-10 encompasses the method of claims 1-10 of the patent. However, the patent claim is obvious from the instant claim because the patent claim is directed to one specific embodiment encompassed by instant claims 8-10. The patented product is included in instant claims 8-10. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor included a method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor said antibody linked to a cytotoxin. The patented claims if infringed upon would also result in

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infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

5h. Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-23 of U.S. Patent No. 5,674,494. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 16-23, of U.S. Patent No. 5,674,494 (having the common inventor with the instant application), claims a method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor. In instant claims 8-10, a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor is claimed. Instant claims 8-10 are generic to claims 16-23 in the patent and encompasses subject matter to which the allowed claims are a species because a method as recited in claims 8-10 encompasses the method of claims 16-23 of the patent. However, the patent claim is obvious from the instant claim because the patent claim is directed to one specific embodiment encompassed by instant claims 8-10. The patented product is included in instant claims 8-10. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of inhibiting allograft rejection by administering a substance that has specific affinity to the IL-2 receptor included a method of inhibiting allograft rejection in a mammal by administering an antibody to the IL-2 receptor. The patented claims if infringed upon would also result in infringement of the broad claim of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

### ***Conclusion***



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No claim is allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
March 31, 2004